Docket No.: IMC0004-17CT
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Schutt et al.	:	Examiner : M. Hartley
Appl. No.	:	10/029,712	:	Group Art Unit : 1616
Filed	:	December 19, 2001	:	
For	:	MIXED GAS MICROBUBBLE COMPOSITIONS	:	

DECLARATION OF ERNEST G. SCHUTT, M.S., UNDER 37 C.F.R. 1.132

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Ernest G. Schutt, M.S., hereby declare as follows:

1. I am an inventor of the invention disclosed and claimed in U.S. patent application Serial No. 10/029,712 entitled "MIXED GAS MICROBUBBLE COMPOSITIONS".

2. As an inventor, I am familiar with the disclosure of the above-identified U.S. patent application, having been actively involved with the conception and reduction to practice of the invention disclosed therein.

3. I received my Bachelor of Science degree in Chemical Engineering in 1971 from the University of Illinois, Urbana, Illinois. I received my M.S. in Chemical Engineering from Clarkson College of Technology, in 1973. From 1982-1990, I was employed as a research scientist at Ortho Diagnostic Systems, in Raritan, New Jersey. In 1990, I became employed by

Alliance Pharmaceutical Corp., San Diego, California, researching products for approximately 10 years. My research has focused on the development of ultrasound contrast agents and fluorochemical based pharmaceutical products. On June 18, 2003, Photogen Technlogies, Inc. purchased Imagent assets, including products, patents, patent applications and personnel. Since that time, I have been employed by Photogen. In 2004, Photogen Technologies, Inc. changed its name to IMCOR Pharmaceutical Co. I currently serve as the Senior Director of Product Research and Development at IMCOR.

4. I have authored a number of papers relating to the development and use of ultrasound contrast agents and am named as an inventor or co-inventor on more than 35 issued United States patents and pending applications, most of which are directed to fluorochemical pharmaceutical technology and ultrasound imaging agents. I am a member of the American Chemical Society and the American Institute of Chemical Engineers.

5. I have reviewed the Official Action pertaining to the above-identified application dated November 10, 2004. The Examiner has asserted that my invention is unpatentable for lack of written description. In the Official Action, the Examiner rejected claims 1-20 of the above-identified application under 35 USC § 112, first paragraph, asserting that the invention was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the present invention. Claims 8, 9, 18, and 19 were also rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. More specifically, the Examiner rejected claims 1 and 10 asserting that the specification failed to describe the limitation that gas B is present in an amount of 50-99% by volume in claim 1, or the 0.5-50% by volume as set forth in claim 10.

7. I disagree with the Examiner's rejections for the following reasons: An understanding of the inherent properties and physical phenomena of gases is important to the instant claimed

invention. In particular, the Ideal Gas Law (PV=NRT), which governs the inherent properties of all gases, states that, for a given set of temperature and pressure conditions, i.e., the temperature and total pressure of a gas is inside a container (including a bubble), the volume of the gas is directly proportional to the number of moles of the gas in the container. This can more easily be seen by rearranging the equation to: **V=N×(R×T/P)**.

Where:

V is the volume of the gas

N is the number of moles of the gas

R is the gas constant

T is the temperature of the gas, and

P is the total pressure on the gas

This equation shows that **V** is proportional to **N** with a proportionality constant of **(R×T/P)**. Therefore, any ratios of moles, e.g. mole fractions, are equal to the same ratio as a volume fraction because the proportionality constants **(R×T/P)** cancel out.

For the purposes of this declaration, we will call this proportionality constant ***K***.

***K*=(R×T/P)**

Making the Ideal Gas Law: **V=N×*K***

8. The composition of a mixture of gases (gas A and gas B) can be defined by specifying the ratio between the moles of gases A and B in the mixture, for example: 200 to 1 can be written as 200:1. This same mixture of gases can also be defined as a mole fraction of gas B where the balance is gas A. The mixture would contain 0.004975124 as the mole fraction of B (moles of B over total moles or 1/201) and expressed as a mole percentage would contain 0.50% mole percent of B.

9. If **Na** and **Nb** are the number of moles of gas A and B in a mixture respectively, then the mole fraction of B is **Nb/(Na+Nb)**. Alternatively, If **Va** and **Vb** are the volumes of gas A and B in a mixture respectively, then the volume fraction of B is **Vb/(Va+Vb)** or volume of B over the total volume. If we substitute the above Ideal gas Law equations:

Va=Na×(*K*)

$Vb=Nb\times(K)$

into the above definition of volume fraction of B, we get:

Volume fraction of B = $(Nb\times K)/[(Na\times K)+(Nb\times K)]$

which equals $(Nb\times K)/[K\times (Na+Nb)]$

which equals $Nb/(Na+Nb)$ or the definition of the mole fraction of B.

Thus the mole fraction of B equals the volume fraction of B

10. The above example (taken from the specification of the instant application) of a mixture defined as a 200:1 mole ratio of A to B, or 0.50% mole percent of B is also defined as containing 0.50% of B by volume.

It also follows that a ratio of A to B of:

1:1 is 50% B by volume, 1/(1+1)

1:100 is 99% B by volume, 100/(1+100)

200:1 is 0.5% B by volume, 1/(200+1)

The above mole ratios are stated in the description as being preferred and by the basic principle of the Ideal Gas Law are shown to be the same as the volume percentages of the claims.

11. Therefore, since the mole fractions are the same as the volume fractions of each gas, the volume percentage limitations recited in claims 1 and 10 are always and necessarily present in the specification of the instant patent application. More specifically, claims 1, and 10 are both supported by page 4, paragraph 13 of the specification disclosing a mixture of gases inside microbubbles, "wherein the first gas and the second gas are respectively present in a molar ratio of about 1:100 to about 1000:1", which, under the Ideal Gas Law equals 99% B to about 0.1% B. Further, page 15, paragraph 49 of the specification reiterates these molar ratios and presents further preferred values for the mixture of gases A and B that can readily be converted by the skilled artisan to volume percentages using the Ideal Gas Law. All of the volume percentages recited in the claims are always and necessarily present in the specification of the instant patent application.

12. I, Ernest G. Schutt, further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Codes, and that such willful false statements may jeopardize the validity of the application for any patent issuing thereon.

Dated: March 08, 2005

By: Ernest G. Schutt, M.S.
Ernest G. Schutt, M.S.